## **REMARKS**

In the Office Action mailed June 15, 2005, the Examiner rejected Claims 1-5, 7-9 and 16-27 under 35 U.S.C. §103(a) as being unpatentable over the newly-cited reference of U.S. Patent No. 6,788,790 to Leysieffer in view of U.S. Patent No. 6,554,762 to Leysieffer and U.S. Patent No. 6,154,023 to Durand. Applicant submits that the noted claims are allowable over the cited art and requests reconsideration by the Examiner.

In this regard, in addressing Claims 1 and 20 in the Office Action, the Examiner has properly recognized the following shortcomings of Leysieffer '790:

"Leysieffer '790 does not disclose a measurement device to measure a magnetic field generated by the implanted hearing aid actuator in response to the electrical signal to generate at least one test measure of the electrical signal; or [that] a signal processing unit [is configured] to process the at least one test measure to assess at least one performance parameter of the implanted hearing aid." Page 5, Lines 20-22 through Page 6, Lines 1-2 of Office Action.

However, the Applicant disagrees with the Examiner's statement that "Leysieffer '790 generally indicates a desire to obtain an objective and quantitative measure of the coupling quality of an interface between an implanted hearing aid actuator and a middle-ear ossicle of a patient". Page 6, Lines 3-5 of Office Action. Rather, and in reference to the "objective audiometric methods" referred to in Leysieffer '790, Leysieffer '790 states that:

"[T]he major disadvantage, among others, is that these objective audiometric methods can only be of a qualitative nature, delivering essentially only data at the auditory threshold and/or only to a limited extent above threshold, and in particular, have only inadequate quantitative accuracy in frequency specific measurements." (emphasis added) Column 2, Lines 11-16.

In turn, Leysieffer '790 states that:

"The <u>primary objective</u> of this invention is to devise a partially or fully implantable hearing system which makes it possible, while <u>circumventing</u> these <u>defects</u> by <u>psychoacoustic measurements, i.e., by subjective patient responses, to determine the coupling quality of the electromechanical transducer to the middle or inner ear. . . ." (emphasis added) Column 2, Lines 23-28.</u>

Applicant submits that the Examiner's above-noted shortcomings of Leysieffer '790, coupled together with Leysieffer '790's own above-noted critique of "objective audiometric methods" and Leysieffer '790's own corresponding "primary object" establish a clear basis for concluding that Leysieffer '790 actually teaches away from any combination with prior art that provides for the objective assessment of implanted hearing aid actuator coupling.

Next, in further addressing Claims 1 and 20 in the Office Action, the Examiner properly recognized the following shortcoming of Leysieffer '762:

Leysieffer '762 does not disclose that the test device [of Leysieffer '762] is (completely) separate from and positionable external to a patient having the implanted hearing aid, nor that the measurement device measures a magnetic field generated by the implanted hearing aid actuator. . . . " Page 7, Lines 3-6 of Office Action.

However, Applicant disagrees with the Examiner's assertion that "[i]n view of . . . the teachings of Leysieffer '762, one of ordinary skill would have sought alternate methods to obtaining externally a measure of the actuator impedance of a partially-implanted hearing aid system of the type taught by Leysieffer '790". Page 8, Lines 16-19 of Office Action. Rather, Leysieffer '762 actually references the application that matured into Leysieffer '790 as a method for determining the quality of coupling of an electromechanical transducer to the middle or inner ear . . . by psychoacoustical measurements, i.e. by subjective patient replies (Column 5, Lines 53-56), and states that:

"[T]he discussed methods for examining the coupling quality of the electromechanical transducer or transducers are disadvantageous in that . . .a subjective evaluation of the patient influences the result . . . [and] lead to unreliable measuring results and hence do not represent an optimum solution . . . ." (emphasis added) Column 6, Lines 23-29.

In turn, Leysieffer '762 states that:

A primary object of the present invention is to devise an at least partially implantable hearing system which permits in a particularly reliable manner an objective measurement of the coupling quality even during operation." (emphasis added) Column 6, Lines 33-36.

Applicant submits that the Examiner's above-noted shortcomings of Leysieffer '762, coupled together with Leysieffer '762's own above-noted critique of subjective evaluation methods and Leysieffer '762's own corresponding "primary object", establish a clear basis for concluding that

Leysieffer '762 actually teaches away from any combination with prior art that provides for subjective assessment of implanted hearing aid actuator coupling, i.e. such as Leysieffer '790.

In short, Applicant submits that one skilled in the art would not be motivated, and would actually be demotivated to combine Leysieffer '790 and Leysieffer '762 since each reference teaches away from the employment of a coupling quality evaluation methodology taught by the other. Further, in teaching away from the utilization of a subjective evaluation methodology, Leysieffer '762 actually references the very patent application corresponding with Leysieffer '790 as an example of a subjective evaluation technique. Indeed, if Leysieffer '762 contemplated that the teachings thereof could have been utilized in combination with the teachings of Leysieffer '790, one would think that Leysieffer '762 would have expressly recognized such combinability given the apparent fact that the sole inventor of Leysieffer '762 and Leysieffer '790 are one in the same, i.e. Hans Leysieffer.

In relation to Durand and the present invention, the Examiner seems to implicitly and properly accept Applicant's prior recognition that such reference fails to disclose or suggest an arrangement in which a test device may be utilized to generate a test signal for use in the assessment of the performance of a hearing aid that includes an implanted actuator, and that Durand fails to make any provision whatsoever for the generation of a test signal. Page 21, Lines 5-9 of Office Action.

However, Applicant strongly disagrees with the Examiner's assertion that in relation to the teachings of Leysieffer '790, Leysieffer '762 and Durand, "the motivation to combine these teachings comes from Durand". Page 21, Line 20 of Office Action. In this regard, and as noted above, Durand fails to disclose or suggest any applicability of the teachings thereof to arrangement for testing the performance of hearing aids that include an implanted actuator. As such, Applicant submits that Durand provides no motivation to one skilled in the art to combine the teachings thereof with the teachings of either Leysieffer '790 or Leysieffer '762. Further, and as noted above, Durand fails to disclose an arrangement in which a test device may be utilized to generate a test signal for use in performance assessment. As such, Applicant submits that such shortcoming provides a further reason why Durand fails to provide any motivation to one skilled in the art to combine the teachings thereof with Leysieffer '762 or Leysieffer '790.

Additionally, and perhaps most importantly, Applicant notes that Durand states that:

"Among the drawbacks in existing current sensing techniques is the requirement of either cutting the conductor carrying the current.... Therefore, it has been deemed desirable to develop a current sensor device which does not require cutting a conductor to insert the sensor device. . . . The present invention contemplates a new and improved current sensor device that overcomes all of the above-noted problems . . . ." Column 1, Line 59 to Column 2, Line 13.

In view of such teaching, Applicant submits that <u>Durand</u> actually <u>teaches away from any combination of the teachings thereof with prior art in which current sensing is achieved by inserting a sensor device into a conductor circuit arrangement, such as that taught by Leysieffer '762. In the latter regard, while the Examiner considers to such teaching of Leysieffer '762 as being "equivalent" to the non-invasive current measurement teachings of Durand (Page 21, Lines 13-16 of Office Action), Applicant submits that Leysieffer '762 actually represents the very, non-equivalent type of current sensing technique <u>that Durand expressly critiques and teaches away from using</u>.</u>

For the record, Applicant notes that it is clear that the prior art must teach or otherwise motivate a combination of prior art references. For example, in the CAFC decision of *In re Anita Dembiczak and Vincent Zinbarg*, 175 F.3d 994, U.S.P.Q.2D (BNA) 1614 (Fed. Cir. 1999) the Court stated:

Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references. See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1352, 48 U.S.P.Q.2D (BNA) 1225, 1232 (Fed. Cir. 1998) (describing "teaching or suggestion or motivation [to combine]" as an "essential evidentiary component of an obviousness holding"); In re Rouffet, 149 F.3d 1350, 1359, 47 U.S.P.Q.2D (BNA) 1453, 1459 (Fed. Cir. 1998) ("the Board must identify specifically...the reasons one of ordinary skill in the art would have been motivated to select the references and combine them"); In re Fritch, 972 F.2d 1260, 1265, 23 U.S.P.Q.2D (BNA) 1780, 1783 (Fed. Cir. 1992) (examiner can satisfy burden of obviousness in light of combination "only by showing some objective teaching [leading to the combination]"); In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2D (BNA) 1596, 1600 (Fed. Cir. 1988) (evidence of teaching or suggestion "essential" to avoid hindsight); Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 297, 227 U.S.P.Q. (BNA) 657, 667 (Fed. Cir 1985) (district court's conclusion of obviousness was error when it "did not elucidate any factual teachings, suggestions or incentives from this prior art that showed the propriety of combination"). See also Graham, 383 U.S. at 18, 148 U.S.P.Q. (BNA) at 467 ("strict observance" of factual predicates to obviousness conclusion required). Combining prior art references without evidence of such a suggestion, teaching, or motivation simply takes the inventor's disclosure as a blueprint for piecing together the prior art to defeat patentability--the essence of hindsight. See, e.g., Interconnect Planning Corp. v. Feil, 774 F.2d 1132, 1138, 227 U.S.P.Q. (BNA) 543, 547 (Fed. Cir. 1985) ("The invention must be viewed not with the blueprint drawn by the inventor, but in the state of the art that existed at the time."). In this case the Board fell into the hindsight trap.

Applicant submits that in the present case the Examiner's combination of Leysieffer '790, Leysieffer '762 and Durand is the result of inappropriate hindsight analysis and, for the various reasons noted above, Applicant respectfully requests withdrawal of the rejection of all pending claims.

In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted,

MARSH FISCHMANN & BREYFOGLE LLP

Ťhomas R. Marsh

Registration No. 31,039

3151 South Vaughn Way, Suite 411

Aurora, Colorado 80014

(303) 338-0997

-10-

Date: 9/15/05